Appeal No. 2013-1568

United States Court of Appeals

for the

Federal Circuit

ROCHE VITAMINS, INC.,

Plaintiff-Appellee,

– v. –

UNITED STATES,

Defendant-Appellant.

APPEAL FROM THE UNITED STATES COURT OF INTERNATIONAL TRADE
IN CASE NO. 04-CV-0175, JUDGE RICHARD K. EATON

BRIEF FOR PLAINTIFF-APPELLEE ROCHE VITAMINS, INC.

ERIK D. SMITHWEISS
ROBERT B. SILVERMAN
JOSEPH M. SPRARAGEN
GRUNFELD, DESIDERIO, LEBOWITZ,
SILVERMAN & KLESTADT LLP
399 Park Avenue, 25th Floor
New York, New York 10022
(212) 557-4000

Attorneys for Plaintiff-Appellee
Roche Vitamins, Inc.

April 30, 2014

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Roche Vitamins, Inc. v. United States

No. 13-1568

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) appellee certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Roche Vitamins, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

DSM Nutritional Products, LLC, as successor to Roche Vitamins, Inc., is the real party in interest.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Roche Vitamins, Inc. has been merged into DSM Nutritional Products, LLC, which is indirectly a wholly owned subsidiary of Koninklijke DSM N.V., which is publically traded.

4. ☑ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Grunfeld, Desiderio, Lebowitz, Silverman & Klestadt LLP: Erik D. Smithweiss, Robert B. Silverman, Joseph M. Spraragen

April 30, 2014
Date

/s/ Joseph M. Spraragen
Signature of counsel

Joseph M. Spraragen
Printed name of counsel

Please Note: All questions must be answered
cc: Patricia M. McCarthy, Esq.

TABLE OF CONTENTS

I. STATEMENT OF RELATED CASES 1

II. STATEMENT OF THE ISSUE 1

III. STATEMENT OF THE CASE SETTING OUT THE FACTS RELEVANT TO THE ISSUES 2

IV. SUMMARY OF THE ARGUMENT 9

V. ARGUMENT 11

A. Standard Of Review 11

B. The Trial Court Correctly Found That The Terms Of Heading 2936 Apply To Betatab 20%. 11

C. The Trial Court Properly Construed Chapter 29 Note 1 And The Explanatory Note To Heading 2936 12

D. The Trial Court Correctly Found That Betatab 20% Meets The Standard Of The Explanatory Notes To Heading 2936. 17

E. Appellant's Contentions That The Ingredients Or Processing Alter The Character Of The Basic Provitamin Product Are Contrary To The Court's Factual Findings And Conflict With The Scope Of Heading 2936. 20

F. The Trial Court's Application Of Note 1(F) Is Consistent With This Court's Precedent. 28

VI. CONCLUSION 32

TABLE OF AUTHORITIES

Cases

BASF v. United States,
391 F. Supp. 2d 1246 *aff'd*, 482 F.3d 1324 (Fed. Cir. 2007) 24
Carl Zeiss, Inc. v. United States, 195 F.3d 1375 (Fed. Cir. 1999) 24
Deckers Outdoor Corp. v. United States, 714 F.3d 1363 (Fed. Cir. 2013) 15
Degussa Corporation v. United States,
508 F.3d 1044 (Fed. Cir. 2007) 10, 28, 29, 30
Home Depot U.S.A., Inc. v. United States,
491 F.3d 1334 (Fed. Cir. 2007) 11
La Crosse Technology, LTD. v. United States,
723 F.3d 1353 (Fed. Cir. 2013) 24
Lonza, Inc. v. United States, 46 F. 3d 1098 (Fed. Cir. 1995) 15
Orlando Food Corp. v. United States, 140 F.3d 1437 (Fed. Cir. 1998) 11
Roche Vitamins, Inc. v. United States,
750 F.Supp. 2d 1367 (Ct. Int'l Trade 2010) ..... passim
Roche Vitamins, Inc. v. United States,
922 F.Supp. 2d 1353, 1363 (Ct. Int'l Trade 2013) ..... passim
Stanley v. Department of Justice, 423 F.3d 1271 (Fed. Cir. 2005) 27

Other Authorities

MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (11th ed. 2003) 16
THE AMERICAN HERITAGE DICTIONARY (5th ed. 2011) 16
WEBSTER'S AMERICAN THESAURUS COLLEGE EDITION (2000) 16
WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (1961) 16

I. STATEMENT OF RELATED CASES

No other appeal in or from the same civil action that is the subject of this appeal was previously before this or any other appellate court. Of the 95 cases listed by appellant, only the following cases will be directly affected by this Court's decision in that they involve substantially identical merchandise: 04-0171; 04-0172; 04-0173; 04-0174; 04-0532; 04-0546; 05-0296; 05-0410; 05-0411; 06-0021; 06-0022; 06-0061; 06-0126; 06-0414; 06-0452; 07-0090; 07-0188; 07-0399; 07-0470; 08-0280; 09-0069; 09-0244; 09-0373; 10-0030; 10-0224; 11-0288; 12-0409; 13-0174; 08-0185; and 11-0067.

Regarding the additional cases listed by appellant, 35 were filed by appellee but involve materially different merchandise. The balance of the listed cases were filed by another importer and cover products other than BetaTab 20%. Of this later class of cases, our review identified five cases that do not appear to involve beta-carotene products, such as 13-00318, which, according to the summons filed in that case, involves the classification of "fish oil products."

II. STATEMENT OF THE ISSUE

The issue raised by this appeal is whether the U.S. Court of International Trade correctly classified "BetaTab 20%," a powder consisting of 20% synthetic beta-carotene (provitamin A) mixed with antioxidants and stabilizers, as a

provitamin under heading 2936, Harmonized Tariff Schedule of the United States (HTSUS).

Appellee disagrees with appellant's Statement of the Issue in several respects. First, nothing in the text of the HTSUS excludes vitamins and provitamins from heading 2936 on the basis that they have undergone processing. The limitation on certain "processing" is found only in the Harmonized Commodity Description and Coding System Explanatory Notes (3d ed. 2002) to heading 2936. Second and more importantly, that Explanatory Note provides that added stabilizers or processing are permitted in goods of heading 2936 where the stabilizers or processing do not alter the character of the basic product to render it particularly suitable for specific use rather than for general use.

Thus, the issue in this case is whether the trial court correctly determined that the stabilizers and processing in BetaTab 20% did not alter the character of the basic provitamin product to render it particularly suitable for a specific use as opposed to general use.

III. STATEMENT OF THE CASE SETTING OUT THE FACTS RELEVANT TO THE ISSUES

Appellant's Statements of the Case and Facts include several factual contentions with which appellee disagrees. While mindful of the limitations set forth in Fed. Cir. R. 28(b), appellee is providing additional, relevant facts that were

established at trial to provide context necessary to respond to certain points raised in appellant's Statement of the Case and Statement of Facts.

The trial court found that the beta-carotene in the subject merchandise is a "provitamin" covered by heading 2936. *Roche Vitamins, Inc. v. United States*, 922 F.Supp. 2d 1353, 1363 (Ct. Int'l Trade 2013) ("*Roche III*")[1] (A27). The court then applied Chapter 29 Note 1(f) as expanded upon in the Explanatory Notes to heading 2936, to determine if the added stabilizers in BetaTab 20% were permitted for goods of heading 2936. Chapter 29 Note 1(f) states, in relevant part, that Chapter 29 applies to the products of heading 2936 (which are referenced in Chapter 29 Note 1(c)) "with an added stabilizer (including anticaking agent) necessary for their preservation or transport."

The Explanatory Note to heading 2936 ("EN 29.36") amplifies the meaning of Chapter 29 Note 1(f) with respect to goods of heading 2936, as follows:

> The products of this heading [2936] may be stabilized for the purposes of preservation or transport:
>
> — by adding anti-oxidants,
>
> — by adding anti-caking agents (e.g., carbohydrates),
>
> — by coating with appropriate substance (e.g., gelatin, waxes or fats), whether or not plasticized, or

[1] For clarity, we are following appellant's convention of referring to the trial court's decision on summary judgment as "*Roche I*" and its decision following trial as "*Roche III*." *See* Blue Br. at 4, N. 2.

> — by adsorbing on appropriate substances (e.g., silicic acid),
>
> provided that the quantity added or the processing in no case exceeds that necessary for their preservation or transport and that the addition or processing does not alter the character of the basic product and render it particularly suitable for specific use rather than for general use.

The legal standard embodied in EN 29.36 was first applied in this case in *Roche Vitamins, Inc. v. United States*, 750 F.Supp. 2d 1367 (Ct. Int'l Trade 2010) ("*Roche I*"). Based primarily on an affidavit of defendant's expert, the trial court denied summary judgment because the affidavit raised "a genuine issue whether the stabilizing ingredients further render BetaTab 20% 'particularly suitable for specific use rather than for general use.'" *Roche I*, 750 F.Supp. 2d at 1382 (A52).

Prior to trial, the parties agreed that in the production of BetaTab 20%, synthetic beta-carotene crystals are mixed with antioxidants and stabilizers to protect the beta-carotene molecules from oxygen and water vapor. Pre Trial Order ("PTO") Sch. C ¶ 16 (A85); A135, 246. The beta-carotene molecules are not modified in this process. PTO Sch. C ¶ 16 (A85). The parties also agreed that the quantity of the anti-oxidants and stabilizers added to the beta-carotene in the subject merchandise is not more than what is necessary to stabilize and preserve the beta-carotene. PTO Sch. C ¶ 38 (A89).

Following a three-day trial, the court entered judgment for Roche. The trial court applied the same EN 29.36 standard as the court in *Roche I*, stating:

> [i]n other words, if the quantity of the stabilizing agent added to an item of this heading is more than is necessary for transport or preservation, or the nature of the stabilizing agent alters the character of the basic product so as to render it "particularly suitable for specific use," the item may not be classified as a provitamin under HTSUS heading 2936.

Roche III, 922 F.Supp. 2d at 1358-9 (A17-8) (citing *Roche I*).

The trial court found as a matter of fact that "the manufacturing process does not change BetaTab's functionality as a provitamin…. [and] does not change the character of the beta-carotene as provitamin A." *Roche III*, 922 F.Supp. 2d at 1362 (A24). The trial court also found as fact that the stabilizing ingredients added to the beta-carotene did not render the product particularly suitable for specific use rather than for general use. *Roche III*, 922 F.Supp. 2d at 1363 (A27).

Appellant's Statement of the Case appears to include several misstatements. Appellant's Brief ("Blue Br.") states at page 3, "[t]he raw material in BetaTab 20% is beta-carotene crystalline, which has multiple general uses [and] … [t]he raw material can be used as Provitamin A for specific therapy …." To the contrary, it was a stipulated fact noted by the court that the "raw material" beta-carotene crystalline has no commercial uses and cannot be used as provitamin A. *Roche III*, 922 F.Supp. 2d at 1362 (A24); in its raw form, beta-carotene crystalline is unstable

and susceptible to oxidation. *See Roche III*, 922 F.Supp. 2d at 1362 (A24); PTO Sch. C ¶¶ 11, 14 (A85). To be commercially usable, either as provitamin A or as a colorant, beta-carotene crystalline must be processed and combined with stabilizing ingredients. *Roche III*, 922 F.Supp. 2d at 1362 (A24); A142, 202-3, 228, 233-4. All of appellant's citations to the record regarding "specific therapy" or other uses pertain not to raw beta-carotene crystalline, as characterized by appellant, but rather to beta-carotene stabilized in a matrix much like that in BetaTab 20%. *See* Blue Br. at 3 (citing A356, 359, 362, 578-79, 710, 715).

Appellant also states that "after trial … the court found, as fact, that the BetaTab 20% ingredients do, indeed, render BetaTab 20% particularly suitable for the specific use of making tablet or capsule forms of dietary nutritional supplements." Blue Br. at 4-5. This is incorrect for two reasons. First, the trial court never stated that the BetaTab 20% ingredients render the product "particularly" suitable for "specific use rather than for general use." What the trial court did find is that the *high concentration of beta carotene* in the product makes it "highly suitable" and "preferable" for use in dietary supplement tablets in contrast to lower concentration beta carotene powders. *Roche III*, 922 F.Supp. 2d at 1361, 1362 (A22, 25).

Second, the evidence introduced at trial and accepted by the trial court as fact established the very opposite of appellant's contention – none of the

ingredients added to the beta-carotene crystalline render the product particularly suitable for tableting. The record reflects the fact that the gelatin and sucrose form a matrix in the shape of a "beadlet"[2] that envelops the beta-carotene and acts as a barrier against oxygen and water vapor. *Roche III*, 922 F.Supp. 2d at 1362 (A24); A134-5. The gelatin and sucrose in BetaTab 20% were not added to prepare the product for tableting. A164-5. The gelatin and sucrose in BetaTab 20% did not play a functional role in the tableting process. *Id*. In fact, BetaTab 20% contains no ingredient that specifically prepares it for use in tablets. A164. BetaTab 20% by itself cannot be formed into tablets. PTO Sch. C ¶ 36 (A88-9). BetaTab 20% first must be combined with tableting excipients, such as microcrystalline cellulose or dicalcium phosphate, to be formed into a tablet. *Id*. Such ingredients are not present in BetaTab 20%. It is for this reason that the court held that "the merchandise contains no ingredients specifically prepared for tableting" *Roche III*, 922 F.Supp. 2d at 1362 (A25); A164.

The trial court found that a stabilizing matrix is necessary for any kind of commercially-usable beta-carotene product. *Roche III*, 922 F.Supp. 2d at 1362 (A24). The trial court found that the stabilizing ingredients did not alter the

[2] Appellant incorrectly refers to the beadlets as "submicron." Blue Br. at 6. The size of the beadlet is in the range of 200-400 micrometers. The size of the beta-carotene particles within the beadlet is "submicron," being in the range of 0.1 to 0.5 microns. PTO Sch. C ¶ 18 (A85); A141.

character of the basic product as provitamin A. *Roche III*, 922 F.Supp. 2d at 1362 (A24). The trial court found that the process "by which Roche adds additional ingredients that envelop the beta-carotene crystalline in a matrix, is common throughout the industry for several types of vitamin." *Id*. The trial court also found no evidence that BetaTab's "non-beta carotene ingredients enhance absorption or bioavailability of the beta-carotene in a manner greater than any other stabilizing matrix." *Roche III*, 922 F.Supp. 2d at 1362 (A24).

The court noted the various uses of Beta Tab 20%, stating that "[t]he merchandise can be used as a source of provitamin A in foods, beverages, and vitamin products, or can be used as a colorant." *Roche III*, 922 F.Supp. 2d at 1361 (A24); PTO Sch. C ¶¶ 23, 29 (A86-7). Evidence established that BetaTab 20% has been used in animal food products and in conventional human foods. A225, 267. Therefore, the trial court's finding that "[i]t was demonstrated as a matter of fact at trial that the BetaTab's additional non-beta-carotene ingredients, added as stabilizers, do not make the merchandise particularly suitable for specific use," is fully consistent with the record. *Roche III*, 922 F.Supp. 2d at 1363 (A27).

The factor that makes BetaTab 20% well-suited or "highly suitable" for fortification applications such as tablets is its relatively high potency, *i.e*., its beta-carotene content as compared to other commercially available beta-carotene products. *Roche III*, 922 F.Supp. 2d at 1361 (A22); A179. Roche's stabilizing

ingredients and processing created a basic beta-carotene powder suitable for various "general" or ordinary uses of beta-carotene. Roche did not further alter this basic product into something "particularly" suitable for a specific end use.

IV. SUMMARY OF THE ARGUMENT

The trial court correctly applied the applicable legal standard in finding that BetaTab 20% is properly classifiable in heading 2936. The legal standard that the trial court applied is the very same standard that was applied by the trial court in *Roche I*, and it is the standard that this Court is now called upon to apply.

The trial court held that BetaTab 20% is properly classified as a provitamin in heading 2936, and that it met the limitations of Chapter 29 Note 1(f) and EN 29.36. The stabilizers added to the beta-carotene to make BetaTab 20% were not more than was required to preserve the beta-carotene, and did not alter the character of the basic product so as to render it particularly suitable for specific use as opposed to general use.

Appellant improperly criticizes the trial court for purportedly creating an incorrect standard for the interpretation of EN 29.36. In doing so, appellant essentially ignores the key operative language of the EN. As properly noted by the trial court, a stabilized vitamin or provitamin is not removed from heading 2936 simply because it is suitable for specific uses in its condition as imported. Rather, as the trial court noted, the stabilizing agents must "alter the character of the basic

product," and it must render the product "particularly" suitable for a specific use "rather than general use." In other words, the stabilizing agents must alter the basic vitamin to become especially or uniquely suited for a specific use instead of being suitable for general uses.

BetaTab 20% clearly satisfies this standard and classification under heading 2936 is appropriate. The product uses the same stabilizers referenced in EN 29.36 ("anti-oxidants," "gelatin" and "carbohydrates"), and they are commonly used in many vitamins. Roche did not further alter this basic product into something "particularly" suitable for a specific end use. The evidence at trial demonstrated that BetaTab 20% is suitable for general use, *i.e.*, for use in tablets, capsules, foods, animal foods, and even as a colorant. PTO Sch. C ¶ 29 (A86); A150-2, 225, 235, 239, 267, 516, 580.

The trial court's decision was fully consistent with this Court's decision in *Degussa Corporation v. United States*, 508 F.3d 1044 (Fed. Cir. 2007). The trial court did not articulate a new standard premised on *Degussa* that would allow an unlimited amount of stabilizer in a chemical of Chapter 29 provided that the chemical can still be used for one of its ordinary uses. Rather, the trial court simply cited *Degussa* as one example in which a chemical can been modified by added ingredients to such an extent that it is no longer classified in Chapter 29.

V. ARGUMENT

A. Standard of Review

This Court's standard of review in a classification case following trial is "*de novo* review to questions of law, including the interpretation of HTSUS terms." *Home Depot U.S.A., Inc. v. United States*, 491 F.3d 1334, 1335 (Fed. Cir. 2007). "Conversely, the ultimate classification of the subject goods is the result of a factual inquiry and is reviewed for clear error." *Id*. Regarding the determination of whether a specific product falls within a given tariff provision, this Court has stated "[t]he second step [of a classification decision] concerns whether merchandise falls within a particular tariff provision, as properly interpreted, and this step is a question of fact that we will not disturb absent clear error." *Orlando Food Corp. v. United States*, 140 F.3d 1437, 1439 (Fed. Cir. 1998).

B. The Trial Court Correctly Found that the Terms of Heading 2936 Apply to BetaTab 20%.

GRI 1 provides that classification is determined according to the terms of any headings and any relevant section or chapter notes. *See* Blue Br. at 16. It was a stipulated fact that beta-carotene is provitamin A. PTO Sch. C ¶ 10 (A84). Therefore, there is no dispute regarding the court's factual finding that the subject

merchandise is accurately described as a provitamin of heading 2936, subject to the limitations of Chapter 29 Note 1(f) and EN 29.36.

Appellant classified the subject goods under heading 2106, which covers "[f]ood preparations not elsewhere specified or included." If the terms of heading 2936 (in accordance with any relevant section or chapter notes) apply to BetaTab 20%, then classification under heading 2106 cannot lie since the product is elsewhere specified. The trial court properly reached this conclusion. *Roche III*, 922 F.Supp. 2d at 1364 (A27).

C. The Trial Court Properly Construed Chapter 29 Note 1 and the Explanatory Note to Heading 2936.

Appellant's main contention is that the trial court misconstrued the phrase "specific use" in a manner contrary to Chapter 29 Note 1. Blue Br. 16-23. Appellant is incorrect. The trial court did not construe the phrase "specific use" in isolation, as appellant would have this Court do. Rather, the trial court interpreted the full text of Note 1 and the EN to heading 2936. Giving effect to all of the relevant text, the trial court determined that the stabilizers and processing of the subject powder did not alter the character of the provitamin to make it particularly suitable for a specific use rather than general use.

Chapter 29 Note 1 provides as follows:

1. Except where the context otherwise requires, the headings of this chapter apply only to:

(a) Separate chemically defined organic compounds, whether or not containing impurities;

(b) Mixtures of two or more isomers of the same organic compound (whether or not containing impurities), except mixtures of acyclic hydrocarbon isomers (other than stereoisomers), whether or not saturated (chapter 27);

(c) The products of headings 2936 to 2939 or the sugar ethers, sugar acetals and sugar esters, and their salts, of heading 2940, or the products of heading 2941, whether or not chemically defined;

(d) Products mentioned in (a), (b) or (c) above dissolved in water;

(e) Products mentioned in (a), (b) or (c) above dissolved in other solvents provided that the solution constitutes a normal and necessary method of putting up these products adopted solely for reasons of safety or for transport and that the solvent does not render the product particularly suitable for specific use rather than for general use;

(f) The products mentioned in (a), (b), (c), (d) or (e) above with an added stabilizer (including an anticaking agent) necessary for their preservation or transport;

(g) The products mentioned in (a), (b), (c), (d), (e) or (f) above with an added antidusting agent or a coloring or odoriferous substance added to facilitate their identification or for safety reasons, provided that the additions do not render the product particularly suitable for specific use rather than for general use;

(h) The following products, diluted to standard strengths, for the production of azo dyes: diazonium salts, couplers

> used for these salts and diazotizable amines and their salts.

Note 1(c) provides that vitamins and provitamins are included in heading 2936 whether or not chemically defined. Note 1(f) states that products described in Note 1(c) (*e.g.*, provitamins of heading 2936) can incorporate "an added stabilizer (including an anticaking agent) necessary for their preservation or transport."

Appellant misspeaks on two counts when it states that Note 1 limits Chapter 29 to those products "whose processing has not rendered them particularly suitable for a specific use." Blue Br. at 16. First, Note 1 is silent as to processing. The limitation on processing is only found in the Explanatory Notes.

Second, appellant neglects to reference the full legal standard that was consistently applied in *Roche I* and *Roche III* and which has its basis in the full text of EN 29.36. That standard provides that a product of heading 2936 may be stabilized for preservation or transport by adding anti-oxidants, anti-caking agents or by coating with appropriate substance (*e.g.*, gelatin, waxes or fats), whether or not plasticized, "**provided** that the quantity added or the processing in no case exceeds that necessary for their preservation or transport and that the addition or processing does not *alter the character of the basic product* and render it particularly suitable for specific use *rather than for general use*." *Roche III*, 922 F.Supp. 2d at 1358 (A17-8) (bold in original, italics added).

When viewed in full, it is clear that the legal standard only excludes stabilizer ingredients or processing where such additions or processing alter the character of the basic product. Furthermore, that alteration must be such as to render the product particularly suitable for a specific use, and no longer suitable for general use. The dispositive factual question, therefore, is whether the character of the vitamin or provitamin product has been altered for a particular specific use. The evidence at trial showed that 1) the beta-carotene's functionality as provitamin A is not altered during the manufacture of the product; 2) the beta-carotene molecules are not modified, and 3) BetaTab 20% remains suitable for general use, *i.e.*, as a source of vitamin A in tablets, hard shell gelatin capsules, chewable tablets, other vitamin products, as well as in foods, beverages and animal food. It can even be used as a colorant in beverages and in foods. *Roche III*, 922 F.Supp. 2d at 1361-2 (A22, 25); PTO Sch. C ¶¶ 28, 29 (A86); A150-2, 225, 235, 239, 267, 516, 580.

Appellant's argument would have the Court ignore key operative language of the EN, which would conflict with the cardinal rule of statutory construction to give effect, if possible, to every word and clause of a statute. *Deckers Outdoor Corp. v. United States*, 714 F.3d 1363, 1367-8 (Fed. Cir. 2013), *petition for cert. filed*, (Jan. 7, 2014) (No.13-803); *Cf. Lonza, Inc. v. United States*, 46 F. 3d 1098, 1109 (Fed. Cir. 1995) (rejecting an interpretation of the Explanatory Notes that

ignored certain text). A provitamin is not excluded from heading 2936 simply because it is "suitable for a specific use," whether that be a vitamin tablet, powder mixture, beverage or a food. To the contrary, one would expect the vitamins and provitamins of heading 2936 to be suitable for a range of end uses. Such is the concept of suitability for general use.

Of importance to a proper construction of EN 29.36 are the meanings of the phrases "particularly suitable" and "rather than." As an adjective, "particular" is defined, in relevant part, as relating to a single definitive thing as opposed to general; distinctive among others of the same kind, out of the ordinary, markedly unusual. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1646 (1961). Common synonyms of "particularly" are "especially," "exceptionally," "unusually," "extraordinarily," "markedly," "notably" and "distinctly." WEBSTER'S AMERICAN THESAURUS COLLEGE EDITION, 519 (2000). The term "rather" is generally defined to mean "to the contrary" or "instead of." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY, 1032 (11th ed. 2003). The phrase "rather than" is generally defined to mean "instead of." *Id.*; THE AMERICAN HERITAGE DICTIONARY, 1460 (5th ed. 2011). Against this background, in order for a product to be rendered "*particularly* suitable for a specific use *rather than* for general use," the product must have been altered to be distinctive or exceptional to that specific end use such that it is no longer considered suitable for general use.

Appellant further errs in stating that "under Note 1(g), any provitamins that contain additives that 'alter the character of the basic product and render [the product] particularly suitable for specific use rather than for general use' are excluded from classification in Heading 2936."[3] Blue Br. at 17. Note 1(g) applies only to an "added antidusting agent or a coloring or odoriferous substance added to facilitate … identification or for safety reasons." Note 1(g) does not broadly apply to "additives" or to the stabilizers mentioned in Note 1(f). Appellant's citation to *Roche I* for this misconstruction does not support such a reading. Rather, in the *Roche I* citation, the court cites to the standard set forth in the Explanatory Notes. *Roche I*, 750 F.Supp. 2d at 1379 (A51). It is that standard of the Explanatory Notes that the trial court applied. Because BetaTab 20% fully meets all elements of this standard, the trial court's decision should be affirmed.

D. The Trial Court Correctly Found that BetaTab 20% Meets the Standard of the Explanatory Notes to Heading 2936.

At trial it was demonstrated that BetaTab 20% meets the standard of EN 29.36. Simply stated, that legal standard provides that stabilizer ingredients are permitted so long as (1) the amount of stabilizers added is not more than necessary for preservation of the vitamin or provitamin, and (2) the stabilizer ingredients and

[3] Appellant raises this argument for the first time on appeal contravening its prior position set out in its principal brief in *Roche I*: "Notes 1(g) and (h) do not appear pertinent to the issues in this case, and will not be discussed." Def.'s Opposition to Pl.'s Mot. for Summary Judgment, pg. 23, N. 8 (A1130).

processing do not alter the character of the basic vitamin product and make the product "particularly" suitable for a specific use as opposed to general use.

As for the first element, the trial court found that the ingredients added to the beta-carotene to create BetaTab 20% constitute a "stabilizing matrix," *Roche III*, 922 F.Supp. 2d at 1362 (A24), and that "BetaTab's additional non-beta-carotene ingredients [are] added as stabilizers" *Roche III*, 922 F.Supp. 2d at 1363 (A27). In addition, the parties stipulated that the stabilizing ingredients added to the beta-carotene do not exceed the quantity necessary for their preservation or transport. PTO Sch. C ¶ 38 (A89). As a result, this issue is not in contention.

The second element is divided into two parts; (1) whether the stabilizing ingredients or processing altered the basic provitamin product, and (2) if so, whether this alteration changed the product to become particularly suitable for a specific end use as opposed to suitable for general use.

In response to the first part of this inquiry, it was stipulated that the process of mixing the raw beta-carotene crystals with the stabilizing ingredients did not alter the beta-carotene molecules. PTO Sch. C ¶ 16 (A85). The government's expert further testified that the processing of beta-carotene into BetaTab 20% does not alter the character of the beta-carotene as provitamin A. A307. Therefore, the trial court properly found as fact that "Roche's manufacturing process does not change the BetaTab's functionality as a provitamin [and] does not change the

character of the beta-carotene as provitamin A." *Roche III*, 922 F.Supp. 2d at 1362 (A24).

As for the second part of the inquiry, the evidence established that neither the ingredients nor the processing used to create the stabilizing matrix of BetaTab 20% was specific to enabling tablet applications. A134. The uncontroverted expert testimony was that sucrose and gelatin function as stabilizers and do not prepare BetaTab 20% for tableting. A165. It was also established that the stabilizers used in BetaTab 20% were essentially the same as those used to stabilize other vitamins, as well as other beta-carotene products that are marketed for a range of uses including use as colorants. A134, 137, 144, 213, 358. "The process used to create the BetaTab, that is, the technology by which Roche adds additional ingredients that envelop the beta-carotene crystalline in a matrix, is common throughout the industry for several different types of vitamin." *Roche III*, 922 F. Supp. 2d at 1362 (A24) (citing A134). The court also noted that the process used to stabilize the BetaTab was the same as that for beta-carotene products used for coloration. *Id*. Therefore, the trial court was correct to find that "the merchandise contains no ingredients specifically prepared for tableting." *Roche III*, 922 F.Supp. 2d at 1362 (A25).

Finally, as to the suitability of the product for general use, the trial court found that BetaTab 20% can be used as a source of vitamin A in foods, beverages

and vitamin products, or as a colorant. *Roche III*, 922 F.Supp. 2d at 1361 (A22). The trial court further found that BetaTab 20% "is well suited for fortifying foods with provitamin A." *Roche III*, 922 F.Supp. 2d at 1362 (A25). The government's expert opined that BetaTab 20% is "suitable for general use as provitamin A." A307. Therefore, the trial court was correct to find that the processing does not alter the beta-carotene to be especially or particularly suited for the specific end use of vitamin tablets to the exclusion of a multitude of uses (be it capsules, food or any other specific application). *Roche III*, 922 F.Supp. 2d at 1362 (A24).

Given the overwhelming weight of evidence that the stabilizing ingredients and method of processing were nothing more than those mentioned in EN 29.36 and are commonly used for vitamins and provitamin A, and did not specifically prepare the BetaTab 20% for tableting, the trial court correctly held that the added ingredients "do not make the merchandise particularly suitable for a specific use" as opposed to general use. *Roche III*, 922 F.Supp. 2d at 1363 (A27).

E. Appellant's Contentions That the Ingredients or Processing Alter the Character of the Basic Provitamin Product are Contrary to the Court's Factual Findings and Conflict with the Scope of Heading 2936.

Appellant's claims that "the ingredients added to create BetaTab 20% made it particularly suitable for tableting" (Blue Br. at 19) and that BetaTab 20% "contains additives that are not used solely for stabilizing and preserving, but also

impart qualities that allow the BetaTab 20% to be suitable for use in making tablets or capsules" (Blue Br. at 21) have no support in the trial court's opinion or in the record of this case. Tellingly, appellant failed to cite any evidence in the record to support these assertions.

Likewise, appellant's assertion that "the trial court overlooked its own findings that the highly processed nature of BetaTab 20% make it particularly suited for the specific use of making a tablet" (Blue Br. at 21) mischaracterizes the trial court's findings, is not supported by any citation to record evidence, and is directly contradicted by the trial court's actual factual findings. The trial court reached the opposite conclusion, namely, that "[the process] by which Roche adds additional ingredients that envelop the beta-carotene crystalline in a matrix, is common throughout the industry for several types of vitamin … [and also] is used to produce all Roche beta-carotene forms," including those used for coloration. *Roche III*, 922 F.Supp. 2d at 1362 (A24). BetaTab 20% by itself cannot be formed into tablets. PTO Sch. C ¶ 36 (A87-8), and it contains no ingredients specifically prepared for tableting. *Roche III*, 922 F.Supp. 2d at 1362 (A25).

Appellant subtly tries to resuscitate its unproven claim that Beta-Tab 20% has enhanced bioavailability or absorption properties beyond those of other stabilized beta-carotene powders that make the product specifically suitable for tableting. Blue Br. at 17-9. However, the trial court soundly rejected this claim.

Roche III, 922 F.Supp. 2d at N. 8 (A27) ("defendant attempted to demonstrate at trial that the stabilizing ingredients made the pelletized crystals more suitable for absorption….to demonstrate that the stabilizers made the BetaTab particularly suitable for a particular use…[but] did not succeed"). While no evidence to support this claim was introduced at trial, it is the case that BetaTab 20% is bioavailable, that is, it is absorbable in the body. This is due to the small particle size of the beta-carotene (A142, 206) and due to the fact that the stabilizing ingredients are themselves water soluble. A145, 206. This is of no consequence, however, as the small size of the beta-carotene particles in BetaTab 20% is common to all commercially usable stabilized beta-carotene products, whether used in tablets, foods or beverages. A142, 237. Likewise, the fact that the stabilizing ingredients are water soluble is immaterial since EN 29.36 expressly allows the use of water soluble stabilizers such as "gelatin" and "carbohydrates," and the use of such stabilizers is common throughout the vitamin industry. *Roche III*, 922 F. Supp. 2d at 1362 (A24).

Appellant asserts that because BetaTab 20% can be described as "water miscible," it necessarily follows that the beta-carotene in BetaTab 20% was "altered by the added ingredients and processing to reduce the water-insolubility of beta-carotene." Blue Br. at 18. From there, appellant argues that the stabilizing ingredients are akin to "water-repellants" which would exclude the product from

heading 2936 based on the Explanatory Note to Chapter 28 Note 1, which applies *mutatis mutandis* to Chapter 29. *Id*. at 19.

The appellant's argument is factually and legally flawed. It is a stipulated fact that the "beta-carotene molecules are not modified in this process [of mixing beta-carotene with the stabilizers]." PTO Sch. C ¶ 16 (A85). None of the experts ever testified that the beta-carotene particles were transformed from insoluble to soluble substances, and the trial court made no such factual finding. Contrary to appellant's unsupported assertion, the water-insolubility of the beta-carotene in BetaTab 20% was not reduced or altered. The trial court simply noted the stipulated fact that BetaTab 20%, as a stabilized powder, is water-miscible. Clearly, EN 29.36 does not preclude the use of stabilizers that are "water miscible." Thus, the fact that the stabilizing ingredients in BetaTab 20% are water miscible is of no legal significance.

Appellant's position runs the risk of excluding all usable provitamin A products from heading 2936. In order for beta-carotene particles to be absorbed in the human intestine, they must be stabilized in a water miscible form. Otherwise, according to the government's own expert, the beta-carotene will not function as provitamin A. A305-6. Surely appellant does not contend that only non-stabilized (and hence non-functioning) beta-carotene crystalline is classifiable in heading 2936, and that once beta-carotene is stabilized in an absorbable form it can no

longer be classified as a "provitamin." Such a restriction would eliminate commercially usable provitamins from heading 2936. The trial court rejected an analogous contention in *BASF v. United States*, 391 F. Supp. 2d 1246, 1256-1257, *aff'd*, 482 F.3d 1324 (Fed. Cir. 2007) ("If only pure, crystalline beta-carotene could be classified under subheading 3204.19.35, as Defendant suggests, the subheading would be an empty provision since pure beta-carotene cannot be used as a colorant without processing.").

Appellant's argument that "the added stabilizers [that] render BetaTab 20% miscible necessarily altered the beta-carotene's character for purposes of Chapter 29" (Blue Br. at 19) also runs afoul of the well-established principle that, "absent contrary legislative intent, HTSUS terms are to be construed according to their common and commercial meanings . . . ." *La Crosse Technology, LTD. v. United States*, 723 F.3d 1353, 1358 (Fed. Cir. 2013), *citing Carl Zeiss, Inc. v. United States*, 195 F.3d 1375, 1379 (Fed. Cir. 1999). In contrast to many of the headings of Chapters 28 and 29, heading 2936 does not provide for raw chemicals. Rather, the terms of heading 2936 cover "vitamins" and "provitamins." The tariff speaks in the language of commerce and cannot be read to exclude commercially usable provitamin A, absent a clear contrary statutory direction. EN 29.36 reinforces this very point, as it clearly covers vitamins with added stabilizers that are "suitable for … general use." This is particularly relevant here because "raw" beta-carotene

crystalline cannot be used as provitamin A. Beta-carotene must be stabilized with ingredients like those in BetaTab 20% in order to function as provitamin A, *Roche III*, 922 F.Supp. 2d at 1362 (A24); (A305-306), and this fact is clearly reflected in EN 29.36.

Appellant states that "BetaTab 20% is processed to a degree that it is fit for specific use as a nutritional ingredient for use in vitamin tablets and capsules." Blue Br. at 4. Appellant's statement hardly supports reversal of the trial court. One would expect that a vitamin or provitamin of heading 2936 would normally "be fit for use in" or even "well-suited" for use in making vitamin tablets, among other general uses of vitamins. It would seem disingenuous to argue that heading 2936 must be restricted only to vitamins imported in a condition not fit for one of the most important uses of vitamins, namely, vitamin tablets. A vitamin with added stabilizers necessary for its preservation cannot be excluded from classification as a "vitamin" simply because it is highly suitable for use in making vitamin tablets. Rather, to be excluded, the added stabilizers must be more than necessary for preservation (stabilization), or must go so far so as to *alter* the basic vitamin product into something particularly suitable for a specific use as opposed to general use.

In other words, the legal standard requires that to be excluded from heading 2936, the vitamin product needs to have been altered to dedicate the product for a

specific end use, for example, through the addition of tableting excipients. The trial court found as fact that BetaTab 20% contains only commonly used stabilizers and does not contain tableting excipients or any other substance specifically to prepare the product for tableting. *Roche III*, 922 F.Supp. 2d at 1362 (A25); PTO Sch. C ¶ 36 (A87-8).

Failing to establish that the beta-carotene is altered for a specific end use, appellant highlights the fact that BetaTab 20% is marketed to the dietary supplement industry. *See* Blue Br. at 16. However, the primary reason that Roche markets BetaTab 20% as a beta-carotene powder for use in dietary supplements, including tablets, has nothing to do with the product's stabilizing ingredients, which are basically the same as those used with beta-carotene powders used in foods and as colorants. *Roche III*, 922 F.Supp. 2d at 1362 (A25). As the trial court recognized, BetaTab 20% is marketed for use as a beta-carotene ingredient for dietary supplements for the simple reason that relative to other stabilized beta-carotene powders, BetaTab 20% has a high concentration of beta-carotene. *Roche III*, 922 F.Supp. 2d at 1361 (A22) ("a higher potency beta-carotene product is preferred for the manufacture of tablets in the dietary supplement industry."); A348-365.

A manufacturer seeking to deliver a certain quantity of beta-carotene in a tablet would require a lesser quantity of BetaTab 20% than it would of a powder

having a lower concentration of beta-carotene (*e.g.*, beta-carotene 10%). A260. In other words, using a lower-concentration beta-carotene product to create a high-potency tablet could result in an undesirably large tablet. A170. That said, customers can certainly use Roche's lower concentration beta-carotene powders, such as its beta-carotene 10% products, in tablets and Roche markets these lower-concentration powders for such use. A160-1. "BetaTab" is merely a brand name; many customers refer to the product simply as "beta-carotene 20%." A269-70.

Thus, while neither the stabilizing ingredients nor its processing have altered the BetaTab 20% to be <u>particularly</u> suitable for tableting instead of general use, it is marketed for use in tablets and capsules precisely because it contains a relatively high concentration of provitamin A. This cannot be a basis for excluding BetaTab 20% from heading 2936 since that would be tantamount to arguing that a stabilized provitamin cannot be classified in the "provitamin" provision because it contains too much provitamin. This faulty logic is contrary to the terms of Note 1 to Chapter 29 and if given effect would impermissibly result in heading 2936 being an empty provision as to provitamin A. *See Stanley v. Department of Justice*, 423 F.3d 1271, 1274 (Fed. Cir. 2005) (declining to adopt a reading of one statutory provision that would render another statutory provision meaningless).

F. The Trial Court's Application of Note 1(f) is Consistent with this Court's Precedent.

The trial court's holding that BetaTab 20% is not excluded from heading 2936 by operation of Note 1(f) is consistent with this Court's decision in *Degussa Corporation v. United States*, 508 F.3d 1044 (Fed. Cir. 2007). In *Degussa*, the Court was asked to determine whether certain modified silicon dioxide products were excluded from heading 2811 by operation of Note 1(a) to Chapter 28. The silicon dioxide products at issue were the result of chemically reacting silicon dioxide with silanes or silicon oil. *Degussa*, 508 F.3d at 1046. As a result of this chemical reaction, hydrocarbon moieties were bonded to the surface of the silicon dioxide and the silanol groups on the surface of the product were reduced by 30% to 70%. *Id*. This modification caused the finished product to be hydrophobic (water-repellent); untreated silicon dioxide is hydrophilic (water-attracting). *Id*.

Note 1(a) to Chapter 28 permits "impurities," and the importer argued that the added silanes or silicon oil were permissible impurities. However, the Explanatory Notes to that chapter note provide that impurities deliberately left in the product to render it particularly suitable for specific use rather than for general use are impermissible. The Explanatory Notes to Chapter 28 Note 1(a) also specifically excluded "water-repellents" "since such agents modify the original characteristics of the products." The Court held that the addition of hydrocarbon moieties was not a permitted impurity because it was a deliberate addition intended

to modify the nature of the silicon dioxide (from hydrophilic to hydrophobic) and because the addition was an added "water-repellent." *Id*. at 1049.

The trial court's decision in *Roche III* is fully consistent with *Degussa*. First, *Degussa* concerned the extent of allowable impurities under Chapter 28 Note 1(a) and not added stabilizers under Chapter 29 Note 1(f). Roche has never asserted that the stabilizers in the subject merchandise can be considered "impurities" under the Note 1(a), and thus *Degussa* is of marginal relevance to the present case. Moreover, the silicone dioxide in *Degussa* was altered through a chemical reaction. In contrast, it is a stipulated fact that the beta-carotene molecule in BetaTab 20% was not modified. PTO Sch. C ¶ 16 (A85). This stipulated fact alone is dispositive of appellant's contention and unequivocally distinguishes *Degussa*. Unlike the production of the modified silicon dioxide products in *Degussa*, the addition of the stabilizing ingredients here does not entail a chemical reaction. Thus, the "original characteristics" of the beta-carotene remain unchanged and there is no "transformation that renders the product suitable for a specific use." *See Degussa*, 508 F.3d at 1049. The trial court decision is fully consistent with *Degussa*.

The Explanatory Notes to Chapter 29 do not reference water-repellants so that restriction of Chapter 28 would only apply to Chapter 29 *mutatis mutandis*.

To the extent that the Explanatory Notes to Chapter Note 1 to Chapter 28 regarding "water-repellants" apply to Chapter 29, it needs only to be mentioned that BetaTab 20% contains no water repellents. Appellant's references to water-repellence are inapposite. *See* Blue Br. at 19, 24.

In its effort to find fault with the CIT's holding, the appellant incorrectly suggests that the trial court has introduced a new standard into Note 1 to Chapter 29. The appellant states that "the court erroneously read the exclusionary language 'particularly suitable for specific use' to mean particularly suitable for use outside the ordinary use of a chemical under Chapter 29." Blue Br. at 22. The trial court did cite *Degussa* for the proposition that a product "becomes 'particularly suitable for specific use' … when (1) the ingredients added to it facilitate uses not ordinary to the goods of the heading, or (2) where the added ingredients alter the chemical's reactive properties in a way that excludes uses ordinary to the goods of that heading." *See Roche III,* 922 F.Supp. 2d at 1359 (A18). These statements do not reflect a new standard and in any event are accurate, as either circumstance would normally exclude a product from heading 2936. The court did not say that these were the only instances where the ingredients added to a provitamin or a vitamin would exclude such products from Chapter 29. At no point did the trial court suggest that additives may be used with abandon in a vitamin or provitamin without regard to the limits of Chapter 29 Note 1(f) and the corresponding EN.

The record clearly supports the trial court's findings that neither the additional stabilizing ingredients nor the process by which those ingredients are added to the beta-carotene alter the character of the beta-carotene to make it "particularly" suitable for specific use "rather than" for general use. Therefore, the trial court correctly held that Note 1 to Chapter 29 does not exclude BetaTab 20% from heading 2936.

Finally, nothing in the trial court's decision suggests that, in the future, the court will apply a new standard that disregards the limits of Note 1(f) and EN 29.36 when considering added stabilizers. *Contra* Blue Br. at 23. The fact that the trial court applied the identical standard that was used in *Roche I* and which is consistent with this Court's precedent belies appellant's assertion.

VI. CONCLUSION

For the foregoing reasons, the trial court correctly held that BetaTab 20% is classifiable under heading 2936. Roche Vitamins respectfully urges the Court to affirm.

Respectfully submitted,

GRUNFELD, DESIDERIO, LEBOWITZ,
SILVERMAN & KLESTADT LLP
Attorneys for Plaintiff-Appellee
399 Park Avenue, 25th Floor
New York, New York 10022
Tel. (212) 557-4000
Fax: (212) 557-4415

/s/ Joseph M. Spraragen
Erik D. Smithweiss
Robert B. Silverman
Joseph M. Spraragen

Dated: April 30, 2014
New York, New York

CERTIFICATE OF SERVICE

I certify that I am over 18 years of age and not a party to this action, and that on Wednesday, April 30, 2014, on behalf of Plaintiff-Appellee Roche Vitamins, Inc., I caused the annexed Brief to be filed via CM/ECF. It is my understanding that notice of this filing will be sent to all counsel of record by operation of CM/ECF and that all parties may access this filing using the Court's electronic filing system.

Upon the Court's acceptance of the electronically filed brief, I have directed that six paper copies shall be timely filed via Federal Express with the Court. I have also directed that two courtesy copies be sent via Federal Express to counsel for appellant-defendant.

GRUNFELD, DESIDERIO, LEBOWITZ,
SILVERMAN & KLESTADT LLP

/s/ Joseph M. Spraragen
Joseph M. Spraragen

Dated: April 30, 2014
New York, New York

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32, I hereby certify that the foregoing brief complies with the Rules of this Court in that it contains 7,408 words including text, footnotes, and headings. This word count is within the limit of 14,000 words set forth in Fed. R. App. P. 32(a)(7)(B)(i).

GRUNFELD, DESIDERIO,
LEBOWITZ, SILVERMAN &
KLESTADT LLP

/s/ Joseph M. Spraragen
Joseph M. Spraragen

Dated: April 30, 2014
New York, New York

8938403_1